IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Norfolk Division

LIFENET HEALTH,

Plaintiff,

v. **Civil Action No. 2:13cv486**

LIFECELL CORPORATION,

Defendant.

OPINION AND ORDER

This matter is before the Court upon Defendant LifeCell Corporation's ("Defendant" or "LifeCell") Motion for New Trial or in the Alternative Remittitur, Doc. 415, and Motion for Judgment as a Matter of Law, Doc. 419 (hereinafter "Motions"). A hearing was held on Thursday, January 29, 2015. Ruling from the bench, the Court **DENIED** the Motions as to divided infringement and the jury instruction concerning the References Cited and took the remainder of the Motions under advisement. For the reasons stated herein, the Court **DENIES** the Motions in their entirety.

I. BACKGROUND

A. Overview of the Patent Claims

United States Patent No. 6,569,200 ("the '200 patent") was issued on May 27, 2003 and is titled "Plasticized Soft Tissue Grafts, and Methods of Making and Using Same."

The '200 patent contains fifteen (15) claims, five (5) of which are independent (Claims 1–3, 7, and 15). Plaintiff asserted claims 1–4, 7–8, and 10. Doc. 65 at 4. These claims are reproduced below.

- ***Claim 1:*** A plasticized soft tissue graft suitable for transplantation into a human, comprising:

  a cleaned soft tissue graft having an internal matrix; and

  one or more plasticizers contained in said internal matrix;

  said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 2:*** A plasticized soft tissue graft, comprising:

  a cleaned, soft tissue graft; and

  one or more plasticizers, wherein said cleaned soft tissue graft is impregnated with one or more plasticizers, and said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 3:*** A plasticized soft tissue graft, comprising:

  a cleaned, soft tissue graft comprising one or more plasticizers, and said one or more plasticizers are not removed from an internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 4:*** The soft tissue graft of any one of claims **1, 2, 3,** wherein said soft tissue graft is suitable for direct transplant into a human without rehydration.

- ***Claim 7:*** A method for producing a plasticized soft tissue graft suitable for transplantation into a human, comprising:

  impregnating a cleaned, soft tissue graft with one or more plasticizers to produce a plasticized soft tissue graft, and said one or more plasticizers are not removed from said internal matrix of said plasticized soft tissue graft prior to transplantation into a human.

- ***Claim 8:*** The method of claim **7**, said step of impregnating, comprising:

  incubating said cleaned, soft tissue graft with a plasticizer composition comprising one or more plasticizers and one or more biocompatible solvents.

- ***Claim 10:*** The method of claim **8**, wherein incubating comprises soaking said cleaned, soft tissue graft in said plasticizer composition.

The Court construed eight (8) disputed terms in the above claims as follows:

Disputed Term	The Court's Construction
"plasticized soft tissue graft"	a load-bearing and/or non-load-bearing soft tissue product, including skin, pericardium, dura mater, fascia lata, and a variety of ligaments and tendons composed of an internal matrix where free and loosely bound waters of hydration in the tissue have been replaced with

	one or more plasticizers without altering the orientation of the collagen fibers, such that the mechanical properties, including the material, physical and use properties, of the tissue product are similar to those of normal hydrated tissue
"suitable for transplantation into a human"	No further construction needed
"cleaned"	a process during which cellular elements and small molecular weight solutes are removed
"plasticizer"	biocompatible compounds which are soluble in water and can easily displace/replace water at the molecular level
"said one or more plasticizers are not removed from [an/said] internal matrix of said plasticized soft tissue graft prior to transplantation into a human"	No further construction needed
"impregnating" / "impregnated"	filling or filled
"without rehydration"	without hydrating a plasticized soft tissue graft prior to implantation into a patient
"incubating"	soaking or otherwise exposing

Doc. 122 at 14. The Court also adopted the parties' agreed constructions for the following three (3) terms:

1. **internal matrix:** the intercellular substance of such soft tissue including for example ligaments and tendons, including collagen and elastin fibers and base matrix substances

2. **plasticizer composition:** composition which includes one or more plasticizers and one or more biocompatible solvents

3. **biocompatible solvents:** any solvent material which does not provoke an adverse response in the patient

Id. at 7.

B. Summary of the Patent[1]

The functioning of the '200 patent may be described as follows. It is unique and advanced

[1] The jury's verdict having resolved disputed factual issues and opinions in favor of Plaintiff, the facts, the expert opinions, and the reasonable inferences therefrom, are viewed in the light most favorable to Plaintiff.

the science in several ways. Its "cleaning" of the tissue removes cellular matter including DNA, and it is the DNA in the tissue graft which causes the transferee's body to reject the tissue graft. After this cleaning, the tissue contains what is defined as its internal matrix, and the tissue with its internal matrix is "impregnated" with a preservative, which the patent refers to as a "plasticizer," thereby creating a "plasticized soft tissue graft." "Plasticized soft tissue grafts" are packaged in their respective containers by both Plaintiff and Defendant. Plaintiff's container includes a solution with water, 30% glycerol, and biocompatible solvents, while Defendant's contains water and "solution E," which contains water and a variety of chemical preservatives including glycerol and biocompatible solvents. The function of their respective preservatives is the same. Plaintiff's product utilizing its '200 patent is packaged "ready to use," as the preservative/plasticizer keeps the soft tissue graft sterile, hydrated, and in retention of its properties as normal hydrated tissue. For the same reasons, Defendant's products Strattice, AlloDerm RTU, Conexa, and GraftJacket RTU are "ready to use." The evidence does not establish whether Plaintiff's products produced in accordance with the '200 patent are more or less effective than Defendant's products which utilized solution E.

In addition to packaging their products in the preservative/plasticizer, their respective products can be stored at room temperature for periods of time up to three (3) years. Prior to the granting of Plaintiff's '200 patent, there were tissue grafts on the market, including Defendant's products, which were sterile and biocompatible; however, these products did not possess all of the features of being "ready to use," being storable at room temperature, and offering an extended shelf life. Instead, such grafts were freeze-dried or fresh-frozen and had to be hydrated, defrosted, or otherwise prepared for use by the surgeon. Coordinating product readiness and the surgeon's readiness was difficult.

The jury found that Defendant's products, Strattice, AlloDerm RTU, Conexa, and GraftJacket RTU, directly infringed the '200 patent, and the patent was not invalid for obviousness, anticipation, or lack of enablement. It fixed Plaintiff's damages at a lump-sum royalty of $34,741,971. Notably, Defendant's sales records for AlloDerm RTU ("ready to use") demonstrated that it captured 75% of the market from its own freeze-dried AlloDerm RTM product in a period of two years. See PTX-087. The original AlloDerm RTM was itself sterile and biocompatible, but Defendant's AlloDerm RTU and its other three infringing produces added the very features the '200 patent brought to the marketplace: ready to use, storable at room temperature, and an extended shelf life. Defendant countered with a survey that it claimed showed the most important features of its products were not the features of the '200 patent; however, the survey did not show what Defendant claimed, but instead merely showed that surgeons preferred a product that works. Moreover, the survey did not ask the crucial question of whether the patented features were what caused surgeons to switch from Defendant's freeze dried products to its new "ready to use" products. See DTX-177.

C. Procedural History

On September 6, 2013, Plaintiff filed a one-count Complaint alleging that Defendant had infringed the '200 patent. Doc. 1. An eleven-day jury trial commenced on November 3, 2014 and proceeded in four phases. In phase one, Plaintiff presented evidence of infringement and damages. In phase two, Defendant presented evidence of non-infringement, damages, and its invalidity defenses. In phase three, Plaintiff was given the opportunity to rebut Defendant's evidence of non-infringement and damages, and it presented its defense to LifeCell's invalidity contentions. Finally, in phase four, Defendant was allowed to offer rebuttal evidence as to invalidity. The Court granted a Rule 50 motion filed by Defendant as to the issue of willful

infringement. Accordingly, the jury was tasked with resolving the issues of infringement, invalidity, and damages.

On November 18, 2014, the jury returned its verdict, awarding Plaintiff damages in the amount of $34,741,971. On November 20, 2014, judgment was entered in that amount, in addition to Plaintiff's costs of action. Doc. 395.

On December 18, 2014, Defendant moved for judgment as a matter of law or, in the alternative, a new trial. Docs. 415, 419. Plaintiff filed its oppositions on January 2, 2015. Docs. 431, 432. Defendant filed its reply briefs on January 8, 2015. Docs. 433, 434. As directed by the Court, Defendant filed a supplemental submission on February 5, 2015. Doc. 460. Plaintiff filed a responsive supplemental submission on February 12, 2015. Doc. 466.

II. LEGAL STANDARD

In a patent case, the Federal Circuit applies the law of the regional circuit on matters of procedural law. Wordtech Sys., Inc. v. Integrated Network Solutions, 609 F.3d 1308, 1318–19 (Fed. Cir. 2010).

A. Motion for Judgment as a Matter of Law

Rule 50(b) of the Federal Rules of Civil Procedure allows a party to renew, within twenty-eight (28) days after the entry of judgment, a motion for judgment as a matter of law made pursuant to Rule 50(a) that was not granted by the Court. Fed. R. Civ. P. 50(b). Rule 50(a) explains that such a motion "must specify the judgment sought and the law and facts that entitle the movant to the judgment." Fed. R. Civ. P. 50(a)(2). The Court may grant such a motion if it finds "that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on [the relevant] issue." Fed. R. Civ. P. 50(a)(1). The Court may not, however, "disturb the verdict where there was sufficient evidence for a reasonable jury to find in the non-movant's favor."

Dotson v. Pfizer, Inc., 558 F.3d 284, 292 (4th Cir. 2009). In deciding whether to grant a motion for judgment as a matter of law, the Court must view the evidence "in the light most favorable to the prevailing party." Id.

B. Motion for a New Trial

Rule 59(a)(1)(A) allows the Court, on motion, to grant a new trial "after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court[.]" Fed. R. Civ. P. 59(a)(1)(A). A "decision on a motion for a new trial rests within the sound discretion of the trial court." City of Richmond v. Atlantic Co., 273 F.2d 902, 916 (4th Cir. 1960).

In the Fourth Circuit, on a motion for a new trial it is the duty of the trial court to set aside the verdict and grant a new trial if "(1) the verdict is against the clear weight of the evidence, or (2) is based upon evidence which is false, or (3) will result in a miscarriage of justice, even though there may be substantial evidence which would prevent the direction of a verdict." Atlas Food Sys. & Servs., Inc. v. Crane Nat'l Vendors, Inc., 99 F.3d 587, 594 (4th Cir. 1996). The first and second prongs are factual determinations. Fairshter v. American Nat'l Red Cross, 322 F. Supp. 2d 646, 650 (E.D. Va. 2004) (citing Atlas Food Sys. Servs., Inc., 99 F.3d at 594). "The third prong requires a policy analysis under which the 'judge's unique vantage point and day-to-day experience with such matters lend expertise.'" Id. (quoting Atlas Food Sys. Servs., Inc., 99 F.3d at 594). On a Rule 59 motion, the Court "may make credibility judgments in determining the clear weight of the evidence." Lovell v. BBNT Solutions, LLC, 295 F. Supp. 2d 611, 618 (E.D. Va. 2003) (citing Knussman v. Maryland, 272 F.3d 625, 647 (4th Cir. 2001)).

III. DISCUSSION[2]

A. Infringement of the '200 Patent

In phase one, Plaintiff presented its evidence of infringement, upon which it bore the burden of proof by a preponderance of the evidence. The jury found in favor of Plaintiff that Defendant's accused products infringed upon the asserted claims. The major dispute as to infringement centered on whether plasticizers were removed from the internal matrix of Defendant's products by soaking the grafts in a saline solution for two minutes, as stated in Defendant's Instructions for Use ("IFU").

The jury's verdict is supported by substantial evidence that plasticizer was not removed from the internal matrix of the graft. There is no dispute that Defendant introduced testing showing removal of plasticizers from the skin graft. See DTX-256 (showing removal of 25-30% of certain plasticizers from Strattice at two minutes); DTX-365 (showing removal of 20-50% of certain plasticizers from AlloDerm RTU at two minutes). Dr. Kaplan testified, however, that the plasticizers removed did not come from the internal matrix, because "[i]f you've removed the plasticizer from the internal matrix, the matrix will no longer have the right mechanical properties to match native structure tissue and function." Tr. at 467:17–24. Obviously, removing the tissue from the packaging containing the liquid preservative in which it is stored will remove some of the plasticizer from the surface of the tissue, but that does not mean it is also removed from the internal matrix.

Dr. Kaplan also testified why the two-minute rinse would not remove plasticizers from the internal matrix, offering a detailed description of the science behind the binding of plasticizers,

[2] The Court, to the extent possible has structured this Opinion to correlate with the four phases of trial. Furthermore, many of the arguments that Defendant raised were brought in both the Rule 50 and Rule 59 Motion. Thus, the Court will address arguments brought in both motions in the same section of this Opinion as the standard of review is similar.

and how disrupting the binding would alter the tissue. Id. at 467:13–469:15. In other words, when the preservative is removed from the internal matrix the tissue will deteriorate. He further explained that although the exterior of the graft contains internal matrix materials, the plasticizers "will come out of the graft but it's not part of the matrix." Id. at 583:11–14. In reaching his conclusion, he relied on the "data provided from LifeCell's own documentation" and testified that the "documentation provided all of the needed information on the materials." Id. at 470:6–12.

Defendant's expert, Dr. Badylak, testified that the plasticizers were removed from the internal matrix. Id. at 1130:21. However, the jury was not bound by Dr. Badylak's opinion and instead accepted that of Dr. Kaplan, returning a verdict in favor of Plaintiff. Moreover, the Court also does not find Dr. Badylak a persuasive witness for purposes of Defendant's Rule 59 Motion. Although Dr. Badylak appears to be an exceptionally accomplished scientist, his testimony failed to persuade the Court for three reasons. First, he was argumentative on the stand, advocating as opposed to testifying. See, e.g., Tr. at 1101:16–1102:4 (discussing the "beauty of solution E" when asked if the plasticizers were slippery); id. at 1322:18–19 (referring to LifeCell's data as "our" data). Second, he objected to questions asked by Plaintiff's counsel instead of allowing defense counsel to object. See, e.g., id. at 1344:20–23 (objecting to the form of a question). Third, he openly disregarded the Court's claim construction.[3] See, e.g., id. at 1152:19–1153:21 (disagreeing with the Court's claim construction for impregnating/impregnated).

In support of its Motions, Defendant brought forth five main arguments as to why the Court should rule that it has not directly infringed the '200 patent. First, it argued that it cannot directly infringe product claims 1-4 of the '200 patent because it does not transplant the products into a

[3] As a result of this, Defendant withdrew its infringement defense claiming that the accused products were not impregnated. Tr. at 1242:18–25.

human. Doc. 428 at 2–6. Second, and for similar reasons, Defendant argued that it does not infringe the method claims, 7, 8, and 10, because it does not perform the step of transplantation. Id. at 6–8. Third, Defendant argued that the Court erred in several of its claim constructions and, that under the proper constructions, the evidence cannot support a finding of infringement. Id. at 8–16. Fourth, Defendant argued that, even accepting the Court's constructions, Plaintiff still could not show that the accused products met the "not removed" limitation found in all of the claims. Id. at 9–13; see also Doc. 416 at 10. Fifth, Defendant also objected to three of the jury instructions regarding infringement. Additionally, Defendant argued that the Court's refusal to strike Stephen Kunin's testimony warrants a new trial. The Court addresses each contention in turn.

1. Direct Infringement of Claims 1–4 of the '200 Patent

Claims 1–4 of the '200 patent are product claims. Defendant argued under Rule 50 that it cannot be liable for direct infringement of claims 1–4 because of the "not removed ... prior to transplantation" limitation. Doc. 428 at 3. Defendant argued that it can only directly infringe if it was directly responsible for transplanting the grafts into humans. Id. According to Defendant's theory, the surgeons are the direct infringers. Plaintiff argued that the limitation is met because "the physical properties of those grafts are such that the plasticizers cannot be removed from the internal matrix whether or not the grafts are rinsed."[4] Doc. 432 at 10.

Defendant principally relied on Cross Med. Prods. Inc. v. Medtronic Sofamor Danek, Inc., 424 F.3d 1293 (Fed. Cir. 2005). At issue in Cross Med. was an apparatus claim with the limitation "operatively joined," construed to require that "the interface and the bone segment are

[4] Plaintiff also contended that Defendant waived this argument. Doc. 432 at 8. However, while Defendant did not assert this argument until the end of trial, the issue was raised in the Rule 50 motion heard at the conclusion of phase three. Tr. at 1594:22–1595:5. Accordingly, the Court considered this argument on its merits.

connected and in contact such that the device is effective to perform posterior stabilization." Id. at 1306, 1310–11. The Federal Circuit noted that it was the surgeons, not Medtronic, that joined the interface portion to the bone, thus Medtronic did not directly infringe because it was the surgeons who made the infringing apparatus. Id. at 1311. It was not enough that Medtronic's device was capable of being infringed because the claim required that the anchor face had to be in contact with the bone. Id. Defendant argued that Cross Med. controls because the surgeons are the ones who make the apparatus (the graft) by transplanting grafts into the patients, and there is no evidence of any agency relationship between Defendant and the surgeons. See also Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Techs., 709 F.3d 1348, 1362 (Fed. Cir. 2013) (quoting Akami Techs., Inc. v. Limelight Networks, Inc., 692 F.3d 1301, 1307 (Fed. Cir. 2012) ("'for a party to be liable for direct patent infringement under 35 U.S.C. § 271(a), that party must commit all the acts necessary to infringe the patent, either personally or vicariously.'")).

Plaintiff argued that Cross Med. can be distinguished from this case because in Cross Med. the surgeon completed the manufacturing of the final product. Doc. 432 at 12. In the instant case, Plaintiff argued that the products already satisfy the limitation because its expert, Dr. Kaplan, testified that the two-minute rinse has no effect on the removal of plasticizer from the internal matrix. Id. Thus, the surgeons do not alter the product. Id. The jury's findings of infringement necessarily support the theory that only LifeCell's actions produce the infringing product. Id. Accordingly, because plasticizers were not removed from the internal matrix prior to transplantation, the surgeons did not "make" the product; they used the product as manufactured by Defendant and in accordance with Defendant's instructions.

Defendant also attempted to compare this case to Centillion Data Sys., LLC v. Qwest Commc'ns Int'l, Inc., 631 F.3d 1279 (Fed. Cir. 2011). In Qwest, the accused products consisted of

two parts: "Qwest's back office systems and front-end client applications that a user may install on a personal computer." Id. at 1281. The Federal Circuit agreed with Qwest's position that it did not directly infringe on the patient at issue because it had no control over the personal computer. Id. at 1286. "Supplying the software for the customer to use is not the same as using the system." Id.

Here, however, LifeCell is doing more than supplying a graft; the graft is ready to be used. Evidence is in the record that the two-minute soak did not remove plasticizers from the internal matrix, and thus the surgeons did not "make" the product; they used the product as produced by Defendant. Defendant's own expert, Dr. Badylak, testified that the plasticizers were safe and thus did not have to be removed. See Tr. at 1099:21–1100:1. Moreover, Defendant provided the IFU to the surgeons and further prepared materials and hired speakers to teach surgeons how to use the product. Egan Dep. at 107:02–20; see also PTX-064. Therefore, viewing the evidence and the reasonable inferences therefrom in favor of Plaintiff, Defendant has "made" a product that directly infringes on the '200 patent. Accordingly, the Court **DENIES** the Motion on this ground.

2. Direct Infringement of Claims 7–8 & 10 of the '200 Patent

Defendant moved under Rule 50 for a finding that it did not infringe the method claims of the '200 patent. Again focusing on the "not removed ... prior to transplantation" limitation, Defendant argued it cannot directly infringe these claims because it does not perform all of the steps of the claimed methods; thus, it cannot be liable for direct infringement. Doc. 428 at 6. According to Defendant, no evidence exists that it performed the step of transplanting the graft into a human nor that it directed and controlled the conduct of another party who did so. Id. Plaintiff argued that it claimed a method of producing a graft and that there is no dispute about the evidence showing Defendant produced a graft where plasticizers were not removed from the

internal matrix. Doc. 432 at 13.

"To establish liability for direct infringement of a claimed method or process under 35 U.S.C. § 271(a), a patentee must prove that each and every step of the method or process was performed." Aristocrat Techs., 709 F.3d at 1362. "Thus, 'for a party to be liable for direct patent infringement ... that party must commit all the acts necessary to infringe the patent, either personally or vicariously.'" Id. (quoting Akami Techs., Inc., 692 F.3d at 1307). Accordingly, in the context of a method claim, "a patent holder must establish that an accused infringer performs 'all the steps of the claimed method, either personally or through another acting under his direction or control.'" Id. (quoting Akami, 692 F.3d at 1307). Defendant primarily relied on two cases in support of its argument, Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (Fed. Cir. 2008), and Aristocrat.

In Aristocrat, the patent covered a slot machine game. Aristocrat, 709 F.3d at 1350. In the asserted claims, the player, rather than the game operator, "makes a wager" and performs the step of "activating said user interface at said particular gaming machine by said player during said displaying of said second game to affect the display of said second game[.]" Id. at 1350–51. Thus, to establish infringement, the defendant "must exercise direction or control over a player playing the game." Id. As the operator did not have sufficient control over the player to establish vicarious liability, there was no infringement. Id. at 1363.

Similarly, in Muniauction, the patent covered a computerized system allowing bond issuers to run an auction and bidders to submit bids via the Internet. Muniauction, 532 F.3d at 1323. Thus, the issue was whether "the actions of at least the bidder and the auctioneer may be combined under the law so as to give rise to a finding of direct infringement by the auctioneer." Id. at 1329. The Federal Circuit found that the defendant could not be liable for direct

infringement because it did not perform every step of the methods, nor did it have another party perform the steps on its behalf. Id. at 1330. The fact that defendant "controls access to its systems and instructs bidders on its use is not sufficient to incur liability for infringement." Id.

Thus, according to Defendant, it cannot be liable for infringement here because the surgeons who transplant the grafts complete the process by performing the "method step" of transplantation. Plaintiff argued these cases are "distinguishable because they require steps that must be performed by different entities." Doc. 432 at 14. Moreover, Plaintiff argued that the jury necessarily concluded "that there is nothing that surgeons can do that affects the presence of plasticizer in the internal matrix prior to transplantation." Id. at 14–15.

In the matter at hand, the jury's verdict is based on substantial evidence that plasticizer was not removed from the internal matrix of the graft. See supra p. 8. Thus, as Plaintiff correctly argued, infringement is complete because the surgeons' actions do not remove plasticizers from the internal matrix. While transplantation was relevant to the infringement analysis, because the product would not infringe if plasticizers were removed from the internal matrix, the method itself claims a process for "producing a plasticized soft tissue graft suitable for transplantation into a human." Accordingly, the claim is infringed if the graft was suitable for transplantation, as Defendant's own expert testified. See Tr. at 1098:2–9; 1099:23 (testimony that the preservatives were not harmful). Thus, whereas infringement was not complete in Aristocrat and Muniauction until the users interacted with the systems, here the surgeons were provided a graft that actually infringed and whose method of production infringed. Further, Defendant directed the surgeons on how to transplant the graft in the IFU. Therefore, the Court **DENIES** the Motion as to this ground.

3. Sufficiency of the Evidence

Defendant next argued that under the constructions adopted by the Court, substantial evidence does not support the verdict.

a. "Not removed ... prior to transplantation"

Despite evidence to the contrary, see supra p. 8, Defendant argued under Rule 50 that no evidence exists to support a finding of infringement. Defendant brought forth five arguments in support of this position: (1) the evidence shows removal of plasticizer; (2) Plaintiff had the burden to show that the removed plasticizer did not come from the internal matrix; (3) Plaintiff's infringement argument was inconsistent with the specification of the patent; (4) Plaintiff's infringement argument was inconsistent with the prosecution history; and (5) Plaintiff argued an inconsistent claim construction to the jury. Doc. 428 at 9–13. Under Rule 59, Defendant argued that the clear weight of the evidence shows removal of plasticizer from the internal matrix of the accused products. Doc. 416 at 10.

First, Defendant argued that, based on Defendant's testing, the two-minute rinse provided for in the IFU showed that plasticizer was removed, and Plaintiff presented no contrary evidence. Doc. 428 at 10. Defendant also argued that Dr. Kaplan conceded that the surfaces of the accused grafts contain internal matrix materials and that the evidence showed removal of plasticizer from the surface as well as interior of the graft. Id. Plaintiff argued that substantial evidence shows the rinse does not remove plasticizers from the internal matrix of the graft. Doc. 432 at 17.

In a Rule 50 motion, the Court may not make credibility determinations. Price v. City of Charlotte, 93 F.3d 1241, 1249 (4th Cir. 1996). In order to find that plasticizers were not removed from the internal matrix, the Court would have to make credibility determinations. There is no dispute that Defendant did introduce testing showing removal of plasticizers from the skin graft.

See DTX-256 (showing removal of 25–30% of certain plasticizers from Strattice at two minutes); DTX-365 (showing removal of 20–50% of certain plasticizers from AlloDerm RTU at two minutes). However, there was a dispute as to what the test results show. Dr. Badylak testified that the plasticizers were removed from the internal matrix. Tr. at 1130:21. Dr. Kaplan, however, testified that the plasticizers were not removed from the internal matrix. Id. at 503:10–13; 509:6–11. While Defendant attempted to argue that Dr. Kaplan conceded that the surfaces of the accused grafts are composed of internal matrix material, Dr. Kaplan further explained that the plasticizers "will come out of the graft but it's not part of the matrix." Id. at 583:11–14. Thus, the Court cannot accept Defendant's argument without improperly ignoring the credibility determination made by the jury. See Konkel v. Bob Evans Farms Inc., 165 F.3d 275, 280 (4th Cir. 1999). Dr. Kaplan provided a sufficient basis to find that the plasticizers removed from the graft did not come from the internal matrix; indeed, the effectiveness of the plasticizer as a preservative is based upon its binding to the internal matrix.

Under Rule 59, however, the Court may make a credibility determination. Lovell, 295 F. Supp. 2d at 618. The Court does not find Dr. Badylak to be persuasive on this issue; thus, under the Rule 59 standard, Defendant's argument also does not stand.

Second, but related to the first argument, Defendant argued that Plaintiff had the burden to prove the negative, that plasticizer was not removed from the internal matrix. Doc. 428 at 11. Defendant notes that Plaintiff did not provide its own testing to prove this negative, but merely offered bare, conclusory testimony. Id. Plaintiff argued that Dr. Kaplan's testimony was not bare; he explained the science behind his opinion and testified that Defendant's internal documents contained sufficient data to support his conclusions. Doc. 432 at 17.

Defendant cited to Kim v. ConAgra Foods, Inc., 465 F.3d 1312, 1320 (Fed. Cir. 2006), to

support the proposition that an expert who offers "conclusory testimony" and fails to support his opinion "with any examinations or tests of the actual accused products" should not be credited. However, the finding in Kim was based on "the circumstances of the case[.]" Id. In Kim, the claim language was such that there would be "no infringement where the accused product contains additional, unclaimed ingredients that materially affect the basic and novel properties of the invention." Id. at 1319–20. Thus, the expert in Kim needed provide a basis for determining whether additional ingredients in the accused products had a material effect on the accused product, a loaf of bread. Id.

Here, Dr. Kaplan did not need to make any such determination. As it relates to the "not removed" limitation, he simply needed to determine whether the two-minute rinse, as argued by Defendant, would result in the removal of plasticizer from the internal matrix. Dr. Kaplan relied on the "data provided from LifeCell's own documentation," and he testified that the "documentation provided all of the needed information on the materials." Tr. at 470:6–12. He also testified why the two-minute rinse would not remove plasticizers from the internal matrix, offering a detailed description of the science behind the binding of plasticizers and how disrupting the binding would alter the tissue. Id. at 467:13–469:15. Thus, unlike the expert in Kim, Dr. Kaplan provided a sufficient basis for his opinion, which provides substantial evidence to support the jury's verdict of infringement.

Third, Defendant argued that Plaintiff's "not removed" arguments are contrary to the specification of the '200 patent. Doc. 428 at 11. Defendant hones in one particular passage from the patent:

> Clinical usage of plasticized bone or soft tissue grafts includes direct implantation of the grafts without further processing following removal from the packaging, implantation following a brief washing in sterile isotonic saline to remove any

> remaining traces of plasticizer associated with the immediate surfaces of the grafts, or by implantation following an extended (approximately 1 hour) washing with sterile isotonic saline to remove as much plasticizer as possible.

'200 patent at 12:8–16. Plaintiff countered that the specification only refers to plasticizer from a plasticized soft tissue graft, not the matrix. Doc. 432 at 18.

As Plaintiff argued, Dr. Kaplan's testimony is consistent with the specification. The two-minute rinse is akin to "a brief washing" that removes "traces of plasticizer" from the exterior of the grafts. Moreover, as explained above, if an extended wash were to remove the plasticizers from the internal matrix, Dr. Kaplan testified this would change the characteristics of the graft; in other words, removal of the preservative (plasticizer) would cause the internal matrix of the skin graft to begin to deteriorate. Thus, the specification stating that an hour rinse would "remove as much plasticizer as possible" is consistent with the testimony: it would remove as much as possible without changing the internal matrix or the characteristics of the graft. Dr. Badylak testified that removing as much plasticizer as possible results in better patient outcomes, which is consistent with the specification—removing as much as possible without altering the internal matrix. Tr. at 1341:4–5. Accordingly, Plaintiff's evidence of removal does not run afoul of the specification.

Fourth, Defendant argued that Plaintiff's arguments are inconsistent with the prosecution history. According to Defendant, "[i]f a saline rinse or soak does not sufficiently remove plasticizer to fall outside the asserted claims, then the added limitation would not have distinguished Cavallaro, and the '200 patent would impermissibly read on Cavallaro." Doc. 428 at 12.

The issue of Cavallaro was before the Court at the Markman proceedings, and the Court considered Cavallaro in construing the term "said one or more plasticizers are not removed from

[an/said] internal matrix of said plasticized soft tissue graft prior to transplantation into a human" to need no further construction because "not removed" meant "not removed." Doc. 122 at 10–11. However, Cavallaro was used to support the construction that there could not be "some" removal. Id. Thus, the fact that the two-minute saline rinse does not remove plasticizer from the internal matrix distinguishes Cavallaro, where plasticizers were removed.

Finally, Defendant argued that Plaintiff made an improper argument to the jury, in that Plaintiff focused on the fact "Plaintiff's expert asserted that only so-called 'tightly bound' and 'loosely bound' plasticizers are 'contained in' the internal matrix, and that removal of so-called 'free' or 'bulk' plasticizer from a graft is permitted by the claims." Doc. 428 at 12–13. Defendant also pointed to an inconsistency in Dr. Kaplan's testimony, in which he stated that when the internal matrix was construed to refer to "collagen and elastin fibers and base matrix substances[,]" plasticizers are not actually contained in collagen fibers or "other components." Id. at 13. Moreover, Defendant argued that because the Court construed the term "plasticized soft tissue graft" as being composed of an internal matrix where free and loosely bound waters of hydration have been replaced with one or more plasticizers, it necessarily follows that the free water is in the internal matrix, and thus "free" plasticizer would also be in the matrix. Id.

However, Dr. Kaplan testified that "water freely moves in and out" of the tissue. Tr. at 461:5. The "free and loosely bound waters of hydration" were construed to come from the tissue, not the matrix. Doc. 123 at 14. Thus, the fact that free water, which is not necessarily part of the matrix, is replaced and "free plasticizer" comes in does not mean that Plaintiff subverted the Court's claim construction.

b. "suitable for transplantation into a human without rehydration"

Defendant next argued under Rule 50 that there is no legally sufficient evidence that its

accused products satisfy this requirement as to claim 4. Doc. 428 at 15. Instead, Defendant argued that the evidence shows the accused products are soaked for two minutes, and thus are rehydrated, removing them from this claim limitation. Id.

However, this argument is rebutted by Dr. Kaplan's testimony. Dr. Kaplan testified that Defendant's products did not require rehydration prior to transplantation. Tr. at 529:7–11. Moreover, he testified that Defendant's products were suitable for transplantation into a human. Id. at 528:24–529:2. Thus, following this testimony, the evidence supports the conclusion that the accused products are suitable for transplantation into a human without rehydration.[5]

c. "plasticized soft tissue graft" limitation

Moving under Rule 59, Defendant also argued that "none of the accused products meet the 'plasticized soft tissue graft' limitation because they are stored in a hydrated state, meaning the plasticizers have not replaced free and loosely bound waters of hydration, and because Plaintiff failed to prove that the mechanical properties are similar to normal hydrated tissue." Doc. 416 at 10. Plaintiff countered that LifeCell "ignores the mountains of evidence" to the contrary. Doc. 431 at 18.

The jury's verdict is not against the clear weight of the evidence as to this limitation. At best, there is a credibility dispute between Dr. Kaplan and Dr. Badylak. Dr. Kaplan provided detailed testimony on how the accused products were plasticized soft tissue grafts. Tr. at 482:19–494:17; 500:20–23; 504:8–508:22. Dr. Badylak offered a different opinion as to why the accused products were not plasticized soft tissue grafts. Id. at 1137:14–1139:8. After witnessing both

[5] Dr. Badylak also testified that the components of solution E were non-toxic preservatives, and thus their removal was "not a matter of safety." Tr. at 1098:2–9. He further testified that "the objective of developing solution E as a preservative was to maintain the hydrated state of the original internal matrix" and that it was "the opposite of replac[ing] water in the product or removing water, which would be dehydrating, lyophilization, and other methods." Id. at 1138:23–1139:3.

experts testify live, neither the Court nor the jury agreed with Dr. Badylak on this issue. Accordingly, the Court **DENIES** the Motions as to insufficient evidence of infringement.

4. Claim Construction

Defendant next argued under Rules 50 and 59 that the Court erred in construing some of the claims at issue, and that under the proper constructions, no evidence supports a verdict in favor of Plaintiff. Doc. 428 at 8–15. Moreover, Defendant argued in the alternative that the jury was improperly instructed by the Court's erroneous claim constructions, and thus a new trial is warranted. Doc. 416 at 2.

As a threshold matter, Plaintiff argued that it is improper for Defendant to argue claim constructions in the guise of post-trial motions. Doc. 432 at 16, Doc. 431 at 9. The Federal Circuit has held that "litigants waive their right to present new claim construction disputes if they are raised for the first time after trial." Conoco, Inc. v. Energy & Envtl. Int'l, L.C., 460 F.3d 1349, 1358–59 (Fed. Cir. 2006). Moreover, this Court has found it improper to enter "judgment as a matter of law on a proposed claim construction that was never even presented to, or considered by, the jury." Synthon IP, Inc. v. Pfizer Inc., No. 1:05cv1267, 2007 WL 1075194, at *1 (E.D. Va. Apr. 6, 2007). However, the Federal Circuit has also "allowed district courts in the past to adjust constructions post-trial if the court merely elaborates on a meaning inherent in the previous construction." Mformation Techs., Inc. v. Research in Motion Ltd., 764 F.3d 1392, 1397 (Fed. Cir. 2014). Generally though, post-trial briefing is "not the appropriate context for [a losing party] to reiterate its dissatisfaction with the court's [claim construction] ruling." Avid Tech., Inc. v. Harmonic Inc., C.A. No. 11-1040, 2014 WL 7206301, at *3 (D. Del. Dec. 17, 2014).

a. "said one or more plasticizers are not removed from said/an internal matrix of said plasticized soft tissue graft prior to transplantation into a human"

Under Rule 50, Defendant argued that instead of finding that this term required no further construction, the Court should have found "that there is no partial or full removal of plasticizers from the internal matrix prior to transplantation." Doc. 428 at 9. Defendant argued that as construed, the Court's Markman Opinion, which distinguished incidental removal from deliberate removal, was an improper construction because it required a specific mental state. Id. With its proposed construction, Defendant argued the evidence shows the plasticizer was removed from the internal matrix of the accused grafts. Id. Plaintiff argued that this is a new construction and not proper for the Court to consider. Doc. 432 at 16. Plaintiff also argued that the Court's statements, taken in context and in their entirety, clearly referred to whether plasticizer was removed and not any mental state. Id.

The Court can consider this argument because "no partial or full removal" would simply elaborate and clarify the Court's previous construction. Mformation, 762 F.3d at 1397. However, even if the Court were to accept this construction, the evidence is sufficient to show that plasticizer was not removed from the internal matrix, either partially or fully, so as to support the verdict.[6] See supra pp. 14–19.

In support of its Rule 59 Motion, Defendant also argued that the Court's refusal to clarify that the "not removed prior to transplantation" limitation allowed Plaintiff to make arguments contrary to the claim construction at closing. Doc. 416 at 4. Plaintiff argued its closing argument was consistent with the evidence and the claim construction. Doc. 431 at 12.

[6] The Supreme Court's recent decision in Teva Pharm. USA, Inc., v. Sandoz, Inc., 135 S. Ct. 831 (2015) regarding the applicable standard of review for findings of fact during claim construction does not effect the Court's ruling on Defendant's Motions, which were decided prior to the issuance of the Teva decision, but are being memorialized only after the Supreme Court's ruling.

The offensive statement at closing reads: "But the two-minute rinse that's there, after the rinse, even after 24 hours, Dr. Kaplan testified, there's still preservatives in the internal matrix. They are still there." See Doc. 416 at 4 (quoting Tr. at 1778:22–25). However, this is not against the claim construction nor confuses or misleads the jury. This was consistent with Dr. Kaplan's testimony, who testified that even after twenty-four hours, the plasticizer would still be in the internal matrix. Tr. at 516:1–13. Further, this argument is consistent with the claim construction because the focus is still on removal from the internal matrix. Accordingly, the Court **DENIES** the Motions as to these grounds.

b. Other construed terms

While Defendant offered an alternative construction of the "not removed" claim limitation, Defendant is reiterating its claim construction arguments for the following disputed terms: "plasticized soft tissue graft," "transplantation into a human," "impregnating," and "incubating." Doc. 428 at 14–16. Defendant proposed that the Court adopt the claim constructions it advocated at the Markman hearing. Id. According to Defendant, if the Court were to adopt its Markman positions now, there would be no legally sufficient evidence to support the jury's verdict. Id. Plaintiff argued that it would be improper for the Court to consider these arguments and that under the claim construction the jury was provided, evidence exists to support the verdict. Doc. 432 at 16.

Rather than seek to clarify, which is permitted, Defendant seeks a directed verdict based on constructions previously rejected. This is not proper in a Rule 50 motion. See Hewlett-Packard Co. v. Mustek Systems, Inc., 340 F.3d 1314, 1320 (Fed. Cir. 2003) ("The verdict must be tested by the charge actually given and by giving the ordinary meaning of the language of the jury instruction."); see also Synthon IP, 2007 WL 1075194, at *1 ("should Synthon wish to continue to

pursue its various claim construction arguments ... it must do so before the Court of Appeals for the Federal Circuit on direct appeal.").

Here, the jury heard expert evidence from both parties on the accused products, and substantial evidence exists to support its verdict. Dr. Kaplan testified that the grafts are impregnated by soaking them in solution E. Tr. at 482:19–23, 502:7–12, 505:25–506:15, 523:2–6. He testified that after impregnation with solution E, the result is a plasticized soft tissue graft. Id. at 493:9–14. Dr. Kaplan also testified that the accused products were incubated with a plasticizer composition, namely solution E. Id. at 523:22–525:1. Finally, Dr. Kaplan also testified that the accused products were suitable for transplantation into a human. Id. at 526:2–17. Therefore, the Court **DENIES** the Rule 50 Motion on the basis of improper claim construction.

However, the Court can consider whether the claim constructions were erroneous in a Rule 59 Motion. See Cardiac Pacemakers, Inc. v. St. Judge Medical, Inc., 381 F.3d 1371, 1383 (Fed. Cir. 2004) ("It is well established that when an incorrect jury instruction—such as an incorrect claim construction—removes from the jury a basis on which the jury could reasonably have reached a different verdict, the verdict should not stand."). Defendant, though, is advocating for the same claim constructions that the Court already rejected at the Markman hearing. Compare Doc. 416 at 2–3, with Doc. 123. Moreover, Defendant was offered an opportunity by the Court to advocate for alternative claim constructions at the Final Pretrial Conference, but declined to do so. See Doc. 293 at 54–56. Therefore, the Court stands by its Markman Opinion and **DENIES** the Rule 59 Motion to the extent it seeks a modified claim construction.[7]

[7] To the extent that Defendant is arguing the Court neglected to construe claims in violation of O2 Micro Int'l v. Beyond Innovation Tech., 521 F. 3d 1351 (Fed. Cir. 2008), when the Court rejects the argument of the parties and finds no further construction is needed, O2 Micro is not violated. See Finjan, Inc. v. Secure Computing Corp., 626

5. Jury Instructions

While Rule 59 is generally governed by Fourth Circuit law, "[t]he legal sufficiency of jury instructions on an issue of patent law is a question of Federal Circuit law[.]" Bettcher Indus., Inc. v. Bunzl USA, Inc., 661 F.3d 629, 638 (Fed. Cir. 2011). A new trial should only be granted based on erroneous instructions when "the movant can establish that the instructions were legally erroneous and that the errors had a prejudicial effect." Id. Defendant objects to three of the Court's infringement instructions.

a. "if a product infringes any claim of a patent, a defendant cannot avoid liability for infringement by instructing physicians or other users of the product to alter an infringing device prior to use"

Defendant argued that this instruction is improper because "it erroneously suggested that Defendant's Instructions for Use ("IFUs"), and actions that surgeons take to prepare the accused products before implantation, are not relevant to the question of infringement." Doc. 416 at 5. Plaintiff countered that the instruction was a correct recitation of the law, in that a device need only be capable of infringing. Doc. 431 at 12.

As stated in the Court's summary judgment opinion, "the cases in which the Federal Circuit state that a product only need to be capable of infringing do not apply because the claim language does not state 'need not be removed' but states 'are not removed.'" LifeNet Health v. LifeCell Corp., No. 2:13cv486, 2014 WL 5456521, at *7 (E.D. Va. Oct. 27, 2014). This instruction, however, does not state that the graft only has to infringe part of the time. Moreover, as discussed above, the evidence supports the conclusion that the two-minute rinse does not remove plasticizers from the internal matrix and thus an infringing device was not altered. See supra p. 8. The Court

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F.3d 1197, 1207 (Fed. Cir. 2010) ("Restating a previously settled argument does not create an 'actual dispute regarding the proper scope of the claims' within the meaning of O2 Micro.").

did not err in issuing this instruction, nor did Defendant suffer any prejudice.

b. "LifeCell is liable for infringing LifeNet Health's patent if you find that LifeNet Health has proven that it is more likely than not that LifeCell made, used, imported, offered to sale, or sold the invention defined in at least one claim of LifeNet Health's patent."

Defendant argued that the following instruction was improper because infringement could only occur if, at the time of transplantation, plasticizer had not been removed. Doc. 416 at 6. Thus, Defendant claims the Court erred by including the terms "making, selling, offering for sale, or importing" in this instruction. Id. at 5–6. Plaintiff countered that this is another improper attempt to assert a "divided infringement" theory. Doc. 431 at 13.

Defendant is correct that "in order for a patented invention to be infringed through the sales or offers to sale prongs of § 271(a), whatever is sold or offered for sale must possess every limitation of the asserted claims." Isis Pharm., Inc. v. Santaris Pharm. A/S Corp., No. 3:11cv2214, 2014 WL 2531973, at *4 (S.D. Cal. June 4, 2014) (quoting Transocean Offshore Deepwater Drilling v. Maersk Drilling USA, Inc., 699 F.3d 1340, 1357 (Fed. Cir. 2012) (internal quotation marks omitted)). However, the evidence supports this instruction, as Dr. Kaplan testified that the two-minute rinse does not remove plasticizer from the internal matrix. Thus, even though the jury and the Court had to look at transplantation to determine if plasticizer was removed from the internal matrix, the evidence shows that it was not. Accordingly, Defendant did "sell" a product that possessed every limitation of the claims. Therefore, this instruction was proper.

c. "The fact that some of the accused products may only be in development is not relevant. Commercialization is not a requirement before a product can be found to infringe a patent. Products in development, such as GraftJacket RTU, may infringe even if they are not yet commercialized if they are made or used in some form. However, no royalty damages may be awarded based upon the sales of this product since there is no evidence it

has been sold to date."

Defendant argued this instruction was improper, as there is no "evidence that any products, much less products in development, have ever been transplanted into a human by Defendant...." Doc. 416 at 6. Plaintiff countered that the law only requires a product be made or used, and the evidence shows that GraftJacket was made or used. Doc. 431 at 13.

Instructing the jury on GraftJacket RTU was proper, and further, Defendant cannot show any prejudice. See Bettcher Inds., 661 F.3d at 638–39 (requiring a finding of prejudice before granting a new trial). The jury found that Strattice, AlloDerm RTU, and Conexa all infringed the patent and were commercialized. Even if GraftJacket has not been sold, the jury awarded a lump sum royalty that also covers further infringement. Thus, Defendant is not liable for any additional damages based upon GraftJacket infringing. Therefore, there is no prejudice by instructing as to the commercialization of products in development.[8] Accordingly, the Court **DENIES** the Motion as to the improper infringement instructions.

6. Evidentiary Ruling- Mr. Kunin's Testimony

Finally, in its Rule 59 motion, Defendant argued that it was prejudiced by the testimony of Mr. Kunin. Doc. 416 at 27. Mr. Kunin was Plaintiff's willfulness expert, who testified about a LifeCell patent application that was rejected over one of the patents in the '200 patent family. Id. Even though the Court granted Defendant's Rule 50 motion as to willfulness, Defendant argues it was still prejudiced by Kunin's "irrelevant, confusing, and prejudicial" testimony, particularly because the Court did not allow into evidence LifeCell's '054 patent. Id. at 28. Plaintiff

[8] Although Dr. Bacharach, one of Defendant's witnesses, attempted to deny the existence of GraftJacket, Plaintiff introduced a LifeCell document identifying GraftJacket RTU as the subject of testing. Tr. at 925:13–926:5; see also PTX-160. In a trial brief Defendant alleged that this was actually AlloDerm RTU. Doc. 351 at 7. At best this is a dispute as to whether GraftJacket RTU was actually "made," which the jury necessarily resolved in favor of Plaintiff.

countered that the Court was correct in refusing Defendant's motion during the trial to strike his testimony and should stand by this ruling. Doc. 431 at 30–31.

While Mr. Kunin's testimony may not have been relevant after the Court removed willfulness from the case, it was relevant at the time it was offered. Thus, the Court did not err in refusing to strike the testimony, and any prejudice suffered by Defendant does not warrant a new trial. Mr. Kunin's testimony was limited as to the earlier LifeCell application. Therefore, the Court **DENIES** Defendant's motion as to this ground.

B. Invalidity and Defenses

In phase two of the trial, Defendant presented its evidence alleging its products did not infringe the '200 patent. Defendant also offered evidence that the '200 patent was invalid, on which it bore a burden of proof by clear and convincing evidence.

1. Indefiniteness

In support of its Rule 50 Motion, Defendant renewed its summary judgment argument that claims 1 through 4 of the patent are invalid for improperly including a method step on a product claim. Doc. 428 at 16. The Court stands by the reasoning of its summary judgment opinion, LifeNet Health v. LifeCell Corp., No. 2:13cv486, 2014 WL 5456521, at *7–11 (E.D. Va. Oct. 27, 2014), and **DENIES** the Rule 50 Motion as to indefiniteness.[9]

2. Anticipation

The jury returned a verdict finding that the '200 patent was not anticipated by the Werner ("Werner") and Duran ("Duran") patent applications. The parties only disputed whether Werner

[9] Moreover, the evidence adduced during the trial showed that the two-minute rinse did not remove plasticizers from the internal matrix. See supra pp. 14–19. Thus, when the product is manufactured and sold, it can readily be determined that the product infringes because no action from the user is necessary, further supporting the Court's earlier ruling that the '200 patent is not invalid for indefiniteness.

and Duran disclosed the "cleaned" and "plasticized soft tissue graft" limitations. As to the "cleaned" limitation, Dr. Kaplan testified that the process disclosed in Werner and Duran differed from the '200 patent because either DNA remained or cells were not extracted. See, e.g., Tr. at 1522:22–1523:5 (Werner); id. at 1530:13–21 (Duran). As to the "plasticized soft tissue graft" limitation, Dr. Kaplan testified that the material properties of the Werner and Duran grafts differed from normal tissue and would not have been disclosed either. See, e.g., id. at 1553:18–22 (Werner); 1536:19–1537:6 (Duran).

Defendant, however, argues that despite Dr. Kaplan's testimony, the evidence is insufficient to support the jury's verdict of no anticipation. "To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." Krippelz v. Ford Motor Co., 667 F.3d 1261, 1265 (Fed. Cir. 2012).

a. Werner

As to the cleaned limitation, Dr. Kaplan testified:

> So some of the cell components, the lipids, the grease materials, will be removed in this process, but, in fact, all of the other cell components, the DNA, the RNA, the many different proteins in there, none of that is extracted. In fact, that's usually something that's going to precipitate those components.
> So the Werner patent doesn't really remove all the cell debris, it's only looking at a few aspects of it but not cleaning the material.

Tr. at 1522:22–1523:5. The removal of DNA is the focus of cleaning the cells since the presence of the donor's DNA prevents the tissue from being biocompatible. See id. at 1085:9–14. On cross examination, the following exchange occurred:

> Q: Now, as far as Werner, if we could turn back to DTX 633, you agree that Werner's treatment of the tissue with hydrogen peroxide and acetone will remove cellular elements from the tissue, correct?
> A: I agree there would be some components removed.

Tr. at 1562:6–10. A few questions later, this exchange occurred:

> If you refer to the example in column two at line 50...
>
> A: Thank you. Yes.
> Q: Do you see first it was supplied in salt water?
> A: Correct
> Q: And then it was subjected to hydrogen peroxide for 48 hours?
> A: Yes
> Q: And then it was degreased for four hours?
> A: Yes
> Q: And then the degreased dura mater was rinsed for 12 to 24 hours with water?
> A: Yes
> Q: And that would remove cellular elements from the tissue, correct?
> A: It would remove limited amounts, as we said, of the lipid materials.

Tr. at 1562:13–1563:4. Defendant attempts to cast Dr. Kaplan's testimony as an admission that Werner discloses a process that removes "some of the cell components." Doc. 428 at 19; see also Doc. 416 at 11. Also in support of its argument, Defendant pointed to the testimony of one of Plaintiff's fact witnesses, Bud Brame, who testified that Allowash was not a "decellularizing technology," but rather "a cleaning technique that's used to remove cellular material, fat, for bone as well as our tendon and ligament grafts." Tr. at 415:1–7. The '200 patent's examples of soft tissue grafts use Allowash as the cleaning technology. '200 patent at 22:32–24:2.

On this issue, Defendant's burden of proof is clear and convincing evidence. Accordingly, and contrary to Defendant's argument, Dr. Kaplan's testimony distinguishing the Werner cleaning process is sufficient to let the verdict stand.

As to the "plasticized soft tissue graft" limitation, Dr. Kaplan did admit that the differences in mechanical properties were not "statistically significant," Tr. at 1552:1–9, but he also testified that these differences in Werner were not comparable to "normal hydrated tissue." Id. at 1553:18–22. On cross, Dr. Badylak admitted that Werner used dura and the examples in the '200

patent did not; although, he did say that dura was a soft tissue graft. Id. at 1373:1–17. Dr. Badylak also admitted on cross that the mechanical properties of the graft in Werner have changed. Id. at 1361:23–1362:4.

While Defendant argued that Werner disclosed a "plasticized soft tissue graft" because Werner used the same concentration of plasticizer as did the examples in the '200 patent, and that Dr. Kaplan's testimony attempting to distinguish Werner is mere conclusory testimony contrary to the specification, sufficient evidence exists to support the jury's verdict. There is an expert dispute as to whether this claim limitation is met. Although Drs. Kaplan and Badylak agreed on some issues, to the extent their testimony was conflicting, the jury was entitled to accept Dr. Kaplan's version. Therefore, the Court **DENIES** the Motions as to Werner.

b. Duran

Again, at issue in Duran was whether it disclosed the "cleaned" and "plasticized soft tissue graft" limitations.[10]

As to the "cleaned" limitation, Dr. Kaplan testified that Duran's language of "devoid of living cells ... means the cells are no longer living, but it does not imply the cells are taken out." Tr. at 1530:13–21. He further testified that nothing in Duran describes the removal of the cells. Id. at 1531:10–13. On cross, Dr. Kaplan testified that the solvents in Duran would break down the cell membranes, but would not necessarily extract them. Id. at 1569:14–1570:16. However, on cross examination, Dr. Badylak testified that the Duran cleaning process was "getting rid of the cells." Id. at 1372:2–3. He further testified that the use of "nontoxic, polar and water miscible organic solvents ... would clean the soft tissue of cells." Id. at 1268:18–24.

[10] At trial, the parties disputed whether Duran was a prior art reference. However, at the hearing, Plaintiff argued that this dispute was moot. Accordingly, the Court did not consider whether Duran was or was not prior art.

Defendant now argues that "Dr. Kaplan admitted that Duran discloses processing soft tissue with an organic solvent (acetone) that would remove some cellular components[,]" and that is all that is required by the "cleaned" limitation. Doc. 428 at 20; see also Doc. 416 at 11–12. Plaintiff countered that Dr. Badylak only testified that Duran discloses a tissue "devoid of living cells," which would not meet the claim limitation. Doc. 432 at 25. Plaintiff further argued that Dr. Kaplan stated one of ordinary skill would not interpret this language to understand the graft is cleaned because it does not imply cells are taken out. Id.

Again, the Court is faced with a battle of the experts. Thus, for Rule 50, the Court cannot rule in favor of Defendant without making a credibility determination. Moreover, for purposes of Rule 59, the Court found Dr. Kaplan to be more credible than Dr. Badylak.

As to the "plasticized soft tissue graft" limitation, Dr. Kaplan testified that as taught in Duran, "the mechanical properties are similar to natural hydrated tissue." Tr. at 1568:24–1569:1. He also testified that in the context of Duran, he was unsure that a 50% glycerol solution "would replace free and loosely bound waters of dehydration." Id. at 1569:2–6. On direct, he testified that the Duran specification indicates that the tissue samples were translucent and had a yellowish tint, which indicates that "the treatment has changed the inherent structure that's present[.]" Id. at 1536:19–1537:6.

Defendant argued "Dr. Kaplan admitted that Duran teaches a soft tissue graft preserved in glycerol with unaltered collagen fiber orientation and mechanical properties similar to normal hydrated tissue[.]" Doc. 428 at 21. It further argued that Duran teaches treating soft tissue with a suitable plasticizer that would result in the replacement of free and loosely bound waters of hydration. Id. It also claimed that Dr. Kaplan's testimony about the amount of heparin in Duran would have an effect on plasticization because it is a polysaccharide, and this contradicts the

disclosures of the '200 patent. Id. Plaintiff argued that the heparin argument is not supported by Dr. Badylak's testimony, and that the Duran graft would have altered mechanical properties. Doc. 432 at 20–21.

Dr. Kaplan testified that the color of the graft changed, and the color of the graft would be a type of "physical property" as required by the claim construction. Thus, Dr. Kaplan's testimony provides sufficient evidence for a reasonable jury to find in favor of Plaintiff and shows that the verdict is not contrary to the weight of the evidence. Therefore, the Court **DENIES** the Motions as to anticipation on the basis of Duran.

c. Jury instruction

Defendant objected to the following instruction: "The prior art considered by the Patent Office is listed in the 'References Cited' section on a patent's front page and the prior art, if any, to which the reference cited lead the patent examiner...." Doc. 416 at 7 (quoting Tr. at 1744:16–19). Defendant argued this instruction is in error because the PTO's Manual of Patent Examining Procedure states "that 'all pertinent prior art for printing in the patent' considered by the examiner shall be cited, even prior art 'not relied upon' to reject claims during prosecution." Id. (quoting M.P.E.P. § 707.05, ¶ 7.96). Defendant argued that it was prejudiced because the "instruction mistakenly implied the PTO considered [ ] Werner [ ] and Goldstein ... which are not identified as 'References Cited' in the '200 patent," and that Plaintiff's statements at closing improperly suggested the Patent Examiner considered this prior art. Doc. 416 at 7. Plaintiff countered that the Court's instruction was actually consistent with the MPEP section, the instruction does not state that the Patent Examiner considered Werner or Goldstein, and to the extent there is a dispute between the parties, it was decided by the jury. Doc. 431 at 15.

As a threshold issue, the Manual was never entered into evidence, nor is there any

testimony indicating that it is a learned treatise or there is another basis for the Court to take judicial notice of it. Moreover, the Court included this language because of Defendant's evidence concerning combinations of patents with one another and prior art. See Tr. at 1300:1–10 (discussing combinations of "Goldstein and Werner or Duran" and "Livesey with either Werner or Duran"); see also Tr. at 1698:22–1699:2 (Defendant asking for jury instruction of skill in the art and Werner and skill in the art and Duran). Second, Plaintiff argues that Defendant did not provide a full and complete quotation.[11] In relevant part, the cited section stated: "Allowed applications should generally contain a citation of pertinent prior art for printing in the patent, even if no claim presented during the prosecution was considered unpatentable over such prior art." M.P.E.P. § 707.05, ¶ 7.96 (emphasis added). It is silent as to whether it covers the References Cited on the prior art actually cited on the '200 patent and is thus not dispositive to this issue, the key word being "generally." Moreover, the Court left it to the jury to determine what weight to give to the prior art references. Tr. at 1686:23–1687:7.

Defendant failed to cite to any law in support of its argument. In addition, the Supreme Court has stated:

> the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent. When it is disputed whether the evidence presented to the jury differs from that evaluated by the PTO, the jury may be instructed to consider that question. In either case, the jury may be instructed to evaluate whether the evidence is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence.

Microsoft Corp. v. i4i Ltd. P'ship, 131 S. Ct. 2238, 2251 (2011). This is what occurred in this case. While there was no direct evidence as to what the examiner considered, Plaintiff questioned Dr. Badylak about the fact that while Werner or Goldstein were not listed in the References Cited

[11] Defendant could have perhaps cited an older version of the MPEP; the Court cites the most recent 9th edition.

of the '200 patent, they were listed on the Duran application, which was in the References Cited of the '200 patent. Tr. at 1366:17–1370:4. Furthermore, the Court added the disputed language; Plaintiff did not propose it. As such, there is no foundation to suggest Plaintiff was attempting to create an improper closing argument by submitting the language to which Defendant objects. Doc. 466 at 9–10.

Accordingly, the Court **DENIED** the Motion as to this instruction.

3. Obviousness

The question of obviousness was submitted to the jury, which found that Defendant did not meet its burden of proof of clear and convincing evidence. The jury heard Dr. Kaplan's testimony, in which he stated that the prior art references asserted by Defendant did not render the '200 patent invalid. See, e.g., Tr. at 1540:5–8 (Werner and Goldstein); id. at 1542:6–9 (Werner and Livesey); id. at 1542:24–1543:3 (Duran and Goldstein).

"A patent is invalid for obviousness 'if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" Wyers v. Master Lock Co., 616 F.3d 1231, 1237 (Fed. Cir. 2010) (quoting 35 U.S.C. § 103(a)). "Obviousness is a question of law based on underlying findings of fact." Id. These underlying findings of fact include:

> (1) the scope and content of the prior art, (2) the differences between the prior art and the claims at issue, (3) the level of ordinary skill in the art, and (4) any relevant secondary considerations, such as commercial success, long felt but unsolved needs, and the failure of others.

Id. Here, while the parties disagreed on the level of knowledge a person of ordinary skill in the art ("POSA") should possess, the parties agreed that their differences do not change the analysis. Tr.

at 1179:16–19; 1520:6–9.

Defendant brought forth four combinations it believes establish that the '200 patent is obvious: (1) Werner combined with the knowledge of a POSA; (2) Duran combined with the knowledge of a POSA; (3) Werner in combination with Goldstein or Livesey; and (4) Duran in combination with Goldstein or Livesey; overall, arguing "that a POSA would have been motivated to combine the preservation techniques disclosed in these references with cleaning techniques well-known in the art, and would have expected success in doing so."[12] Doc. 428 at 23; see also Doc. 416 at 13.

Plaintiff correctly claimed that this argument fails in that it "ignores the failure of Werner and Duran to disclose a 'plasticized soft tissue graft[.]'" Doc. 432 at 26. As the jury found that Werner and Duran did not anticipate on the basis of a plasticized soft tissue graft, "simply adding a cleaning procedure to either of the Werner or Duran references would not provide one of ordinary skill in the art with a reasonable expectation of success in meeting the language of the asserted claims due to changes in the mechanical properties of the tissue products." Id. at 28; see also Tr. at 1541:5–22. Dr. Kaplan offered sufficient, credible testimony for the jury to find that the references asserted by Defendant would not have rendered the invention of the '200 patent obvious. Thus, while Dr. Badylak reached the opposite conclusion, the jury was free to determine the credibility of the different opinions. As it pertains to Rule 59, the Court did not find Dr. Badylak credible.

Defendant also objected to two of the obviousness jury instructions. First, Defendant

[12] Defendant also argued that Plaintiff failed to present secondary considerations of non-obviousness. However, as discussed, the failure of Duran and Werner to show a plasticized soft tissue graft precludes a finding of obviousness, regardless of whether or not there are secondary considerations of non-obviousness. Moreover, evidence exists in the record of such secondary considerations, albeit not presented in phase three as directed by the Court. See Tr. at 1301:16–20.

argued that the Court misstated the obviousness combinations asserted by Defendant by reversing the primary and secondary references. Doc. 416 at 8. Plaintiff countered, however, that the Court repeated Defendant's proposed instructions. Doc. 431 at 16.

The Court read the following instruction to the jury:

> LifeCell alleges that the asserted claims of the '200 patent were obvious in light of: One, U.S. Patent 5,336,616 "Livesey" issued on August 9th, 1994 in combination with either Werner or Duran; two, U.S. Patent Number 5,613,982 "Goldstein" issued on March 25th, 1997 in combination with either Werner or Duran; number three, U.S. Patent Number 6,630,001 "Duran" as issued on October 7th, 2003 from a patent application that was filed on June 24th, 1998 or Werner U.S. Patent Number 4,357,274 issued on November 2nd, 1982 combined with the knowledge of cleaning known to those skilled in the art of the subject area of the '200 patent.

Tr. at 1749:10–20. This is substantially similar to Defendant's proposed instructions, which stated "Livesy ... in light of," and "Goldstein ... in light of." Doc. 306 at 59–66. Thus, there is neither error nor prejudice.

Second, Defendant argued that the Court erred in instructing the jury as to secondary considerations of non-obviousness because Plaintiff failed to present any such evidence in phase three of the trial. Doc. 416 at 8. Plaintiff countered that it did present vast amounts of evidence on secondary considerations. Doc. 431 at 16.

As the Court explained at the charging conference:

> I don't recall the expert witnesses talking about secondary considerations, but there was other evidence about commercial, successful, and there are other things about solution to the problem resolved by ready to use, that others failed to solve the problem, evidence that they did, that others copied the claimed invention—evidence in this case that they did.

Tr. at 1662:15–21. While not presented in phase three, evidence of secondary considerations is in the record. See Doc. 431 at 16 (citing testimony in the record).

Therefore, the Court **DENIES** the Motions as to obviousness.[13]

4. Enablement

The jury also considered whether the '200 patent was invalid for lack of enablement, upon which Defendant bore the burden of proof by clear and convincing evidence. Dr. Kaplan testified that one of the plasticizer compounds in the '200 patent could be "prescreened" in two weeks to determine whether the mechanical properties would be similar to normal tissue. Tr. at 1544:4–1545:7. He testified on cross, however, that in order to determine if it would be suitable for transplantation into a human, animal studies would have to be performed, which "would take months." Id. at 1587:22–88:10. He further stated that each plasticizer, each combination, and each soft tissue would have to be screened as well. Id. at 1588:11–20. Furthermore, there are only eighteen plasticizers listed in the specification.

Whether a claim is invalid for lack of enablement is a question of law, and the party asserting invalidity must show clear and convincing evidence supporting the conclusion. Liebel-Flarsheim Co. v. Medrad, Inc., 481 F.3d 1371, 1377 (Fed. Cir. 2007). In order for an invention to be enabled, the specification "must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (internal quotation marks omitted)). "'The scope of [patent] claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is

[13] The Federal Circuit has noted "that the legal determination of obviousness may include recourse to logic, judgment, and common sense, in lieu of expert testimony." Wyers, 616 F.3d at 1239. For example, if technology is simple, no expert testimony is required to support a holding of obviousness, and the factual issues are not in dispute, Judgment as a Matter of Law ("JMOL") as to obviousness can be granted despite a contrary jury verdict. Sundance, Inc. v. DeMonte Fabricating Ltd., 550 F.3d 1356, 1365 (Fed. Cir. 2008). Here, the parties are disputing the material facts of whether the prior art references would lead to a finding of obviousness and whether expert testimony is desirable for the fact-finder to decide the issue, as the technology here is complicated. Thus, this is not a situation where the Court can simply rely on "logic" or "common sense" to enter JMOL in favor of Defendant.

disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.'" Invitrogen Corp. v. Clontech Labs., Inc., 429 F.3d 1052, 1070–71 (Fed. Cir. 2005) (quoting Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1196 (Fed. Cir. 1999)).

Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). These factors include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. The Court considers the In re Wands factors "[a]fter the challenger has put forward evidence that some experimentation is needed to practice the patented claim[.]" Alcon Research Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014).

The parties' dispute focused mainly on this undue experimentation requirement. Defendant's argument centered on the fact that despite listing eighteen suitable plasticizers, which can be used in concentrations of 10-100% by weight/volume, the only examples of plasticized soft tissue grafts in the '200 patent use glycerol at a concentration of 30%. Doc. 428 at 25; see also Doc. 416 at 16. Defendant highlights testimony from Drs. Badylak and Kaplan, which indicate full experimentation to determine if the grafts would be "suitable for transplantation into a human" would take months of work for each compound listed. Id. at 25–26. Plaintiff countered with Dr. Kaplan's testimony that "any experimentation would be simple and routine, involving repetition of techniques in serial that even one of less than ordinary skill in the art could be expected to perform." Doc. 432 at 30.

Defendant cited to Wyeth and Cordis Corp. v. Abbott Labs., 720 F.3d 1380 (Fed. Cir. 2013), in support of its argument. In Wyeth, the Federal Circuit found that "having to synthesize and screen each of at least tens of thousands of candidate compounds constitutes undue experimentation." Id. at 1385. Wyeth's own expert testified that "it would take technicians weeks to complete" assays for each of the candidate compounds. Id. at 1386. Moreover, for simply one of the compounds, the Federal Circuit noted that it would "require a complicated and lengthy series of experiments in synthetic organic chemistry." Id.

However, this case is more analogous to Martek Biosciences Corp. v. Nutrinova, Inc., 579 F.3d 1363 (Fed. Cir. 2009). In Martek, the district court entered JMOL on the basis of invalidity for lack of enablement after the jury had returned a verdict of validity. Id. at 1377. The language at issue concerned "growing euryhaline microorganisms in a fermentation medium, wherein said euryhaline microorganisms are capable of producing..." Id. at 1378. The district court, in entering JMOL, relied on the defendant's expert testimony that this independent claim covered perhaps 10,000 such organisms, while the patent only disclosed one example. Id. at 1378–79. However, the Federal Circuit found that the district court erred in finding the related dependent claims invalid for lack of enablement because Plaintiff's expert testified that the dependent claims cover "only 22 known species." Id. at 1379. Thus, while claim 1 was properly found to not be enabled by the district court because of the vast number of possibilities, "the evidence presented to the jury supports an inference that there are relatively few potential species that may meet the limitations of claims 4 and 5[.]" Id. Accordingly, the Federal Circuit found that "the evidence supports the jury's implicit finding that one need not perform undue experimentation to practice claims 4 and 5, as well as the jury's ultimate conclusion that Lonza failed to provide invalidity of those claims by clear and convincing evidence." Id.

Here, there are 18 plasticizers. While there are different types of soft tissue grafts, the patent discloses two examples of different grafts, and the steps are very similar. '200 patent at 22:35–24:2. Dr. Kaplan testified that prescreening could quickly identify suitable plasticizers in two weeks, and that this testing could be done by students, who have less skill than the POSA submitted by both parties. Tr. at 1544:4–21. This short-time period to determine a suitable plasticizer for plasticization is not unreasonable. See Eli Lilly and Co. v. Actavis Elizabeth LLC, 435 F. App'x 917, 923 (Fed. Cir. 2011) (citing Enzo Biochem, Inc. v. Calgene Inc., 188 F.3d 1362, 1371 (Fed. Cir. 1999)). Moreover, while Defendant argues that not all of the plasticizers listed in the patent can be suitable plasticizers, this does not necessarily require a finding that the claims were not enabled. See Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984) ("Even if some of the claimed combinations were inoperative, the claims are not necessarily invalid."). Furthermore, the failure of LifeNet to develop a commercialized product until 2010 does not compel a finding of a lack of enablement. See Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1309–10 (Fed. Cir. 2012) (finding that the fact the invention had only been tested on pigs at the time of filing provided substantial evidence supporting verdict rejecting enablement defense). Thus, there is sufficient evidence to support the jury's ultimate conclusion, and the verdict is not against the clear weight of the evidence. Therefore, the Court **DENIES** the Motions as to enablement.

5. Marking

In returning its damages verdict, the jury necessarily found that Plaintiff marked its products. The evidence showed that the '200 patent was marked on Plaintiff's three products, not on the exterior of the packaging, but on the IFU located within the packaging. Tr. at 155:11–21, 156:16–157:12, 159:11–160:12; see also PTX 253–55. Mr. Wilson testified on cross that LifeNet

always puts the IFU in its products. Tr. at 175:4–20. Plaintiff's marking contrasts with Defendant's product, where its patent is marked on the exterior of the package. See DPX-012. Defendant argued that this testimony is insufficient "to prove that [LifeNet] complied with the marking requirement at the relevant time, which is the period beginning when Plaintiff began selling its DermACELL, OraCELL, and ArthroFLEX products in 2010 and ending when Plaintiff filed its complaint in September 2013." Doc. 434 at 20.

LifeNet was obligated to comply with the marking statute in order to obtain the benefit of constructive notice since it did not provide actual notice prior to suit. American Medical Sys., Inc. v. Medical Eng'g Corp., 6 F.3d 1523, 1538 (Fed. Cir. 1993). "In determining whether the patentee marked its products sufficiently to comply with the constructive notice requirement, the focus is not on what the infringer actually knew, but on whether the patentee's actions were sufficient, in the circumstances, to provide notice in rem." Nike, Inc v. Wal-Mart Stores, Inc., 138 F.3d 1437, 1446 (Fed. Cir. 1998). The patentee must show "that once marking was begun, the marking was substantially consistent and continuous." Id. As LifeNet asserted both product and method claims, the marketing requirement goes to both after 2010 when LifeNet launched its product line based on the '200 patent. American Medical, 6 F.3d at 1538–39.

Given Mr. Wilson's testimony that LifeNet always includes the IFU, and the fact that the '200 patent was listed on the instructions for all three of LifeNet's products, the evidence supports the jury's finding that LifeNet did continuously mark its products. Thus, LifeNet products were marked, the sufficiency of such marking is an issue for the finder of fact, and the jury has resolved this issue in favor of the Plaintiff for purposes of Defendant's Rule 50 and Rule 59 Motions.[14]

[14] At the hearing, when the Court asked Defendant about the issue of marking the interior of the packaging, counsel replied "we focused in on a slightly different issue, a failure-of-proof issue. And that issue was – is that for marking

Defendant also argued that the Court improperly instructed the jury that Plaintiff need not provide notice for its method claims. Doc. 416 at 9. Plaintiff countered that no notice was needed on the method claims before it produced its own skin graft product line in 2010, and that it marked its products once they were released. Doc. 431 at 18 n.5.

The Court's instruction as to the method claims was "[f]or Claim 7, 8, and 10, the calculation of damages should begin on the date you find LifeCell began infringing the '200 patent." Tr. at 1759:19–21. There was no objection to the marking instruction for the product claims.

The dispute here centers on the fact that when Defendant first introduced Strattice and Conexa, Plaintiff was not selling its own product(s). The Federal Circuit is clear "that the notice provisions of section 287 do not apply where the patent is directed to a process or method." Am. Med. Sys., 6 F.3d at 1538. However, when a patentee is asserting both product and method claims, the patentee must mark the product. Id. Both parties failed to cite, and the Court was unable to find, a Federal Circuit case addressing this precise dispute of infringement of a method claim occurring prior to the launch of a patentee's own product(s).[15]

Regardless of this issue, Defendant cannot show prejudice as to this instruction. The jury found both the method and product claims infringed. The jury was properly instructed that notice was required for the product claims. Moreover, by awarding damages, the jury necessarily found that Defendant was on notice concerning the '200 patent because the jury found that Plaintiff had

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you have to show that it was marked properly through the entire period." Doc. 451 at 88. Thus, as the Court understood Defendant's argument, it was focusing on Mr. Wilson testifying about the current IFU, which it was arguing was insufficient to establish marking for the entire period.

[15] The Federal Circuit has stated that "to the extent that there is a tangible item to mark by which notice of the asserted method claims can be given, a party is obligated to do so if it intends to avail itself of the constructive notice provisions of section 287(a)." Am. Med. Sys., 6 F.3d at 1538–39. Am. Med. Sys. does require LifeNet to mark its products starting in at least 2010, as it asserted both apparatus and method claims.

sufficiently marked its product.

Therefore, the Court **DENIES** the Motions as to marking.

6. Evidentiary Rulings

a. LifeCell's '054 Patent

In its Rule 59 Motion, Defendant argued the Court erred in refusing to allow into evidence the '054 patent, which covers solution E. Defendant argued that its patent was relevant to issues of infringement and secondary considerations of non-obviousness. Doc. 416 at 28. Defendant argued it was further prejudiced by the exclusion of this patent given Mr. Kunin's testimony concerning the rejected application.[16] Id. at 29. Plaintiff countered that Defendant suffered no prejudice because it was allowed to, and did, offer evidence on how solution E was a different preservative or plasticizer, and thus was not covered by the '200 patent. Doc. 431 at 32. Moreover, Plaintiff argued that having one's own patent is not a defense to infringement. Id. Finally, Plaintiff also countered that Defendant wanted to introduce the patent only for an improper purpose, highlighting counsel's opening statement that Defendant did not infringe the '200 patent because it had its own patent. Id.

"[T]he existence of one's own patent does not constitute a defense of infringement of someone else's patent." Vaupel Textilmaschinen KG v. Meccanica Euro Italia SPA, 944 F.2d 870, 879 n.4 (Fed. Cir. 1991). However, the Federal Circuit has also said that "[t]he fact of separate patentability is relevant, and is entitled to due weight." Nat'l Presto Indus., Inc. v. West Bend Co., 76 F.3d 1185, 1192 (Fed. Cir. 1996). Most of the cases, however, have considered the issue of separate patentability in the context of the doctrine of equivalence, which was not an issue

[16] Relatedly, Defendant argued Plaintiff waived its objection to the '054 patent by declining to object to it on Defendant's exhibit list, and further opened the door through the use of the '780 application. Doc. 416 at 29; see also Doc. 460 at 3.

here. See, e.g., Atlas Powder Co., 750 F.2d 1569, 1580–81. Moreover, in Fiskars, Inc. v. Hunt Mfg. Co., 221 F.3d 1318, 1324 (Fed. Cir. 2000), the Federal Circuit faced a similar case, in which the defendant was attempting to present its own patent as a defense. The Federal Circuit did not disturb the district court's exclusion of the defendant's patent because "it is well established that separate patentability does not avoid equivalency as a matter of law[.]" Id.

Here, the Court allowed Defendant to present evidence that its products did not practice the claims of the '200 patent, and also permitted evidence regarding solution E, which is part of its '054 patent. Even conceding the relevance of its patent, the Court can exclude relevant evidence if it misleads the jury, and the Court was on notice that Defendant had such an intent because it stated in its opening statement that it did not infringe because it had its own patent. See Tr. at 107:1–3 ("And we don't infringe because our products, AlloDerm RTU and Strattice, practice our own patented preservation technology."); see also Fed. R. Evid. 403. The context in which the patent was to be introduced in phase two would have improperly suggested it was a defense to infringement; however, the Court never explicitly excluded it. Tr. at 1302:9–10; see also Doc. 466 at 2–4.

Moreover, the Court advised Defendant that it would revisit the admissibility of the patent in phase four. Id. at 1397:14–16. Defendant, however, failed to move for its admission in phase four. Defendant argues that it had no chance to move for its admission because Plaintiff failed to introduce evidence on secondary considerations of non-obviousness during phase three. Doc. 460 at 3. However, the Court could not consider this issue at the trial because of Defendant's failure to even attempt to offer its admission in phase four, and the '054 patent was not admissible upon the issues under consideration when it was offered earlier. Further, the essence of the '054 patent is solution E, which was prominently referred to in the evidence. Accordingly, the Court

DENIES the Motion as to this issue.

b. Scope of Dr. Erdmann's testimony

The last ground Defendant brings in support of its Rule 59 Motion is that the Court erred in prohibiting Dr. Erdmann from testifying as to "the practice of surgeons with respect to the preparation of the accused products for transplantation[.]" Doc. 416 at 29. Defendant argued that how surgeons used the grafts was relevant to infringement, and Dr. Erdmann was the only witness who could testify to how the grafts were actually used. Id. Plaintiff argued that the Court's decision was correct because such testimony would have been speculative. Doc. 431 at 34.

A district court in New Jersey faced a similar issue and excluded an expert from testifying on how physicians make decisions regarding prescriptions. Pfizer Inc. v. Teva Pharm. USA, Inc., 461 F. Supp. 2d 271, 276 (D.N.J. 2006). As the Court stated concerning the scope of Dr. Erdmann's testimony, "[h]e can say what he does and what he tells the students to do ... But he can't get into what the standard is ... he can't say anything that would suggest that there's a standard in the community in which he practices, or nationally, just what he does." Tr. at 829:25–830:10. It would have been too speculative for him to testify as to what all surgeons do.[17] Defendant was permitted to offer testimony concerning surgeons, including Dr. Erdmann and his students, using the two-minute rinse. Therefore, the Court **DENIES** the Motion as to this issue.

C. Damages

The jury was also tasked with deciding the issues of damages. Of particular importance,

[17] The Court also expressed concern that it was entirely possible that surgeons do not follow the instructions, and the instructions also indicated that they were only recommendations. Tr. at 821:25–822:7.

Plaintiff's damages expert, Mr. Gallagher, testified about the "sea change" in sales from Defendant's freeze-dried AlloDerm product to the new "ready to use" AlloDerm RTU. In the span of five years, "ready to use" products increased from thirteen (13) to eighty (80) percent of LifeCell's sales. Tr. at 656:2–11; see also id. at 658:9–21. Mr. Gallagher proposed a running royalty, which could have resulted in an award of approximately $54 million. Id. at 672:7–11. The jury ultimately chose instead to award a lump sum royalty of $34,741,971.

Defendant now offers three grounds in support of its Motions as they pertain to damages: (1) improper use of the Entire Market Value Rule ("EMVR"); (2) that the Edwards offer is insufficient as a base input; and (3) that the verdict was against the clear weight of the evidence. The Court addresses each contention in turn.

1. Entire Market Value Rule

As it asserted during trial, Defendant argued here that Plaintiff's damages theory is foreclosed by the EMVR, as Mr. Gallagher failed to apportion the value of the patented features. Doc. 428 at 27–28; see also Doc. 416 at 16–17. Moreover, Defendant argued that the evidence shows there were multiple non-patented "features" of the graft that lead surgeons to choose the accused products. Doc. 416 at 20. For the same reasons, Defendant objects to the Court's instruction as to damages because it failed to "provide any instruction on how the jury would determine if the accused products qualified under the EMVR." Id. at 9. Plaintiff argued that the EMVR does not apply because the product is "physically incapable of being separated into multiple components," the patent claims the entire skin graft, the "features" Defendant cites are not components as understood by the EMVR, and the graft is the "smallest salable unit." Doc. 432 at 32–33.

"[W]hen claims are drawn to an individual component of a multi-component product, it is

the exception, not the rule, that damages may be based upon the value of the multi-component product." Virnetx, Inc. v. Cisco Sys., Inc., 767 F.3d 1308, 1326 (Fed. Cir. 2014). For this exception to apply, "'[a] patentee may assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially creates the value of the component parts.'" Id. (quoting Versata Software, Inc. v. SAP Am., Inc., 717 F.3d 1255, 1268 (Fed. Cir. 2013)). "In the absence of such a showing, principles of apportionment apply." Id. In a case where the smallest salable unit is "a multi-component product containing several non-infringing features with no relation to the patented feature, the patentee must do more to estimate what portion of the value of that product is attributable to the patented technology."[18] Id. at 1327–28.

First, the Court issued the following instruction as to the EMVR:

> If you conclude that a running royalty is appropriate based on the evidence presented to you, the base used must be limited so as to include only infringing sales and only value that is attributable to the patented features of the '200 patent. Only this portion of the value is subject to the royalty. If the patented features create only a portion of the value of the products, the base should only include the value that is attributable to those patented features.

Tr. at 1762:3–11. This instruction is consistent with the above-body of law.[19]

The case closest to the facts presented here is a district court case, AstraZeneca AB v.

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[18] Defendant attempted to argue that the recent decision in Ericsson, Inc. v. D-Link Sys., Inc., 773 F.3d 1201 (Fed. Cir. 2014), further supported its position. However, Ericsson does not change the body of law at all, but rather reiterates the principles district courts should apply when assessing the applicability of the EMVR.

[19] Relatedly, Defendant argued the Court erred in answering a jury question concerning the royalty base during deliberations. However, Defendant cannot show prejudice to the Court's response to the jury's question, "[w]ill a running royalty percentage be based on gross sales?" Tr. at 1839:22–23. The Court responded that "[t]he running royalty percentage, if you decide on a running royalty, should be based on the sales of the accused products, based on all the evidence and all of the instructions of the Court." Id. at 1847:23–1848:1. The instructions included apportionment, the evidence included Defendant's expert discussing the various "features" of the accused products, and the jury ultimately chose a lump sum royalty as opposed to a running royalty. Thus, while the answer to the jury could have been more involved, even a base other than the sales of the products would have to be selected with an understanding of what the total sales were. Accordingly, there was no error or prejudice in answering the jury's question as the Court did.

Apotex Corp., 985 F. Supp. 2d 452 (S.D.N.Y. 2013). In Astrazenica, the defendant attacked plaintiff's royalty calculations for an infringing sub-coating of a capsule because it relied on the value of the product as a whole. Astrazenica, 985 F. Supp. 2d at 489. The court there rejected defendant's attack, noting that the LaserDynamics line of cases are for "multi-component products" like electronics, and should not be applied in the pharmaceutical context. Id. at 490. Even under the EMVR, while the sub-coating did not create the demand for the product, it did substantially create its value. Id. Because the sub-coating overcame a serious past problem in allowing the drug to pass through the stomach, it was a crucial aspect of the entire product. Id.

Moreover, as Plaintiff also argued, in all of the cases cited by Defendant, the patent only covered the component part and not the entire product.[20] See Virnetx, 767 F.3d at 1314, 1328 (patent covered security over networks used in Apple's iPhone, iPod, iPad, and Mac computers, but damages were based on the market value of the products); LaserDynamics, Inc. v. Quanta Comp., Inc., 694 F.3d 51, 56, 68 (Fed. Cir. 2012) (patent only covered an optical disc drive, but damages were based on the entire computer); Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1297, 1318–19 (Fed. Cir. 2011) (patent only covered Microsoft's Product Activation feature, but royalty was based on sales of Microsoft Office and Windows); Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1337 (Fed. Cir. 2009) (patent at issue covered only the date-picker tool in Microsoft Outlook, but was only "a very small component of a much larger software program.").[21]

Here, the patent covers the graft itself, not just the "features" of the graft. These

[20] Plaintiff also argued at the hearing that when the Federal Circuit refers to features, it is referring to the components of a product, not features such as size and ready-to-use as Defendant argued in support of its damages theory.

[21] The recent case Gaylord v. United States, __ F.3d __, 2015 WL 449192, (Fed. Cir. Feb. 4, 2015), offers further support for Plaintiff's position. In Gaylord, the government attempted to apply the EMVR principle to a copyright case involving an image on a stamp, objecting to the royalty base including the entire value of the stamp. Id. at *7. The Federal Circuit noted that "[t]he stamp consists, essentially in full, of the image of Mr. Gaylord's work and is not a multi-component product in a meaningful sense." Id. Just as the stamp consists almost entirely of the portrait, here the entirety of the product is the graft itself.

electronics cases all involve situations where one piece of a multi-component product led to infringement. Here, the entire graft infringes. Defendant also cited Rembrandt Social Media, LP v. Facebook, Inc., 22 F. Supp. 3d 585 (E.D. Va. 2013), in support. In Rembrandt, the expert apportioned damages, but included in his royalty base revenue for features of Facebook that did not infringe. Id. at 595. This Court found that improper because "[i]f Facebook did not pay Rembrandt to license the patents, it could have continued to use those [ ] features without infringing." Id.

The logic of Rembrandt does not support Defendant's argument. For example, Defendant points to the different sizes of the Strattice and AlloDerm RTU product as a feature that requires apportionment. Doc. 416 at 22. While Facebook could use its non-infringing features without a license, Defendant cannot offer more "sizes" of its accused products without a license because the larger sizes would still infringe. Moreover, the graft was the smallest salable unit and properly used as the royalty base.

Thus, Mr. Gallagher's opinion is not an improper use of the EMVR, and Defendant was not prejudiced by the testimony concerning the sales of the accused products. See Doc. 416 at 18–19. Additionally, Mr. Gallagher did consider whether the "features" that Defendant argues are important in reaching his proposed royalty base. See, e.g., Tr. at 668:2–23 (discussing size and safety). Moreover, Mr. Gallagher provided testimony that the patented feature was the basis for demand and substantially creates the value of the product. See Tr. at 649:4–8, 659:2–5, 668:10–670:2. Therefore, applying both the Rule 50 and 59 standards, the Court **DENIES** the Motions as to the EMVR.

2. The Edwards Offer

One of the bases for Mr. Gallagher's opinion was a proposed running royalty rate of 5% to

Edwards Lifesciences ("Edwards") by LifeNet. Mr. Gallagher explained that while only an offer, the fact that Edwards was not a competitor while LifeCell was would lead the parties in this hypothetical negotiation to consider a higher royalty rate. Thus, the competition feature balances the fact that the 5% running royalty was only an offer. Tr. at 662:13–664:25.

However, Defendant now attacks the use of the Edwards offer for three reasons: (1) Edwards never responded to LifeNet's offer; (2) the offer to Edwards was for a greater scope of rights than would be at issue in this hypothetical negotiation; and (3) Edwards wanted a lump-sum royalty, not a running royalty. Doc. 428 at 28–29; see also Doc. 416 at 24–25. Plaintiff countered that Mr. Gallagher considered more than just the Edwards offer, and that these objections Defendant raised were factors the jury was entitled to consider, and also entitled to reject. Doc. 432 at 34 n.17.

The Edwards offer was an offer for an entire family of patents, of which the '200 patent is a part. While LifeNet and Edwards did engage in lengthy discussions about a possible license, LifeNet ultimately offered a running royalty of 5%. Edwards never responded to this offer. Tr. at 162:4–172:12. While Plaintiff is correct that Mr. Gallagher testified that he considered more than the Edwards offer, his testimony did show it was one of the bases for his expert opinion. See id. at 709:12–710:7.

The Federal Circuit has cautioned against the use of proposed licenses, but has stated that they "may have some value for determining a reasonable royalty in certain situations." Whitserve, LLC v. Computer Packages, Inc., 694 F.3d 10, 29–30 (Fed. Cir. 2012). In Whitserve, the proposed offer had no probative value because the expert was using it to create two contradictory arguments. Id. at 30. Here, Mr. Gallagher was not using the Edwards offer to contradict anything; it is the base input, and he considered other factors, including competition, in

finding that the parties would have agreed to a 5% royalty. Moreover, the jury awarded a lump sum royalty, not a running royalty. Thus, the Edwards offer, combined with the totality of Mr. Gallagher's testimony, is sufficient to support the damages award under both the Rule 50 and 59 standards.[22]

3. Clear Weight of the Evidence

While the jury was entitled to weigh Mr. Gallagher's opinion that a royalty should equal approximately $54 million, it ultimately concluded that the royalty amount should be less. Nevertheless, Defendant argued under Rule 59 that the verdict was against the clear weight of the evidence. Defendant focused on the fact that the jury awarded a lump sum royalty of $34,741,971, well in excess of the $3.8 million lump sum royalty proposed by its expert, Mr. Martinez. Doc. 416 at 26. According to Defendant, because Mr. Gallagher's opinion is not based on sufficient evidence, Defendant should be entitled to a remittitur of damages to $3.8 million or, in the alternative, a new trial. Id. Plaintiff responded that it was permissible for the jury to rely on Mr. Gallagher's opinion to fashion a lump sum royalty, and that moreover, the verdict was consistent with Mr. Martinez's testimony that the revenues attributable to the "Ready to Use" technology were $68.4 million. Doc. 431 at 28.

As a threshold matter, the Court's inquiry as to how the jury arrived at its verdict is hampered by the fact that the parties rejected the Court's proposed verdict form that would have included special interrogatories. The Court initially circulated a draft verdict form that included questions for the jury asking it to explain how, if applicable, it reached a lump sum verdict. Tr. at

[22] Defendant also raised an argument in its Rule 59 Motion that "Mr. Gallagher provided no testimony to demonstrate that this initial offer for a full portfolio reflected what the parties in this case would have agreed upon for licensing just the '200 patent, as required by the hypothetical negotiation." Doc. 416 at 25. However, the testimony does show that Mr. Gallagher considered all of the information in determining what LifeNet and LifeCell would have agreed upon for a royalty in this case.

1628:10–1629:6. When Defendant objected, the Court asked the parties to write out a proposed verdict form. Id. at 1630:21–22. The verdict form jointly submitted by agreement of the parties, and adopted by the Court, did not include any special interrogatories for a lump sum royalty, but only asked the jury to state the amount of the lump sum payment. Doc. 369 at 8; see also Doc. 451 at 83.

Thus, the Court must rely upon the expert testimony of the damages witnesses, which each party presented in determining how the jury reached its verdict. The jury was entitled to weigh the testimonies of Mr. Gallagher and Mr. Martinez to fashion its lump sum award, which falls between the lower of Mr. Martinez's two numbers and Mr. Gallagher's number. The lump sum did not exceed the $54 million opinion of Mr. Gallagher, nor did it exceed Mr. Martinez's statement that "$68 million is the amount attributable to the RTU technology." [23] Id. at 1491:3–4. The jury could have reduced the proposed royalties to account for much of the evidence Defendant offered, such as the Edwards offer being too high. See id. at 1421:18–1422:20 (discussing the initial offer being too high). "'In setting damages, the jury's function is to weigh contradictory evidence, to judge the credibility of the witnesses, and to resolve factual disputes[.]' Finjan, Inc. v. Secure Computing Corp., 626 F.3d 1197, 1212 (Fed. Cir. 2010) (quoting C & F Packing Co. v. IBP, Inc., 224 F.3d 1296, 1304 (Fed. Cir. 2000)). This is what happened here. The jury heard evidence from both experts, credited Mr. Martinez's opinion that the parties would have agreed on a lump sum royalty, considered both experts' opinion as to what damages should be, and ultimately arrived at a conclusion somewhere between the numbers suggested by both sides. Sufficient

[23] Although the Court sustained Plaintiff's objection to Defendant asking about this $68 million figure due to Mr. Martinez's failure to disclose an opinion as to a running royalty, Tr. at 1490:2–1491:8, Defendant failed to conduct re-direct after Plaintiff solicited the $68 million figure on cross examination. Id. at 1491:5–7; see also id. at 1635:9–11 ("Well, you are right that the door was open when they brought that up. They opened the door, but you didn't walk through it.").

evidence exists to support the jury award, and thus the Court **DENIES** the Motions as to damages.

IV. SUMMARY & CONCLUSION

One of the crucial components of the '200 patent is the ability of a preservative to bind with the internal matrix of the soft tissue graft. The patent refers to its preservative as a plasticizer, and Defendant refers to its preservative as Solution E, which contains plasticizers. Both Plaintiff and Defendant store their soft tissue grafts in a liquid that contains their respective preservative/plasticizer. When the soft tissue grafts are taken out of the packaging for the surgeon's use, some of the preservative/plasticizer is left in the packaging and some spills off the exterior of the soft tissue graft. Some of the preservative/plasticizer also escapes from the exterior of the soft tissue graft during Defendant's "two minute soaking" in a saline solution. However, according to Dr. Kaplan, none of this preservative/plasticizer escapes from the internal matrix of the soft tissue graft, and accordingly, the Court ruled at the Markman hearing, and again at trial, that the foregoing processes did not constitute "removal" as the term is used in the '200 patent. This ruling is based upon the language in Claims 1, 2, 3, and 7 of the '200 patent, which state "said one or more plasticizers are not removed from [an/said] internal matrix of said plasticized soft tissue graft prior to transplantation into a human" (emphasis added). Defendant's expert, Dr. Badylak, testified to the contrary, but the Court, and apparently the jury, found Dr. Kaplan's testimony more persuasive than that of Dr. Badylak since it is clear that the binding of the preservative/plasticizer to the internal matrix is crucial to the ability of the soft tissue graft to retain its similarity to a normal hydrated tissue.

Notwithstanding the undisputed fact that it added a preservative/plasticizer to its offending products, Defendant also contends that since a portion of the plasticizer escaped from its offending products as packaged during preparation for surgery, it was no longer a plasticized soft tissue graft

when transplanted. Again, this position is contrary to Dr. Kaplan's testimony and is further undermined by Defendant's withdrawal of its defense based upon the Court's Markman definition of impregnated/impregnating. For purposes of Defendant's Rule 50 Motion, once the jury found that Defendant's offending products were plasticized soft tissue grafts at the time of transplantation and that the plasticizers were not removed from the internal matrix of the soft tissue grafts prior to transplantation, and the Court makes the same findings for purposes of Defendant's Rule 59 Motion, such findings, together with the Court's rulings on the other issues outlined herein, compel the Court to **DENY** Defendant's Rule 59 Motion for a New Trial or in The Alternative Remittitur, as well as Defendant's Rule 50 Motion for Judgment as a Matter of Law.

The Clerk is **REQUESTED** to deliver a copy of this Order to all counsel of record.

It is so **ORDERED**.

/s/
Henry Coke Morgan, Jr.
Senior United States District Judge

HENRY COKE MORGAN, JR.
SENIOR UNITED STATES DISTRICT JUDGE

Norfolk, VA
March 18, 2015